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Via ECF and Email August 13, 2019

The Honorable Katherine Polk Failla
Thurgood Marshall United States Courthouse
40 Foley Square
New York, NY 10007

Re: Discovery Disputes in *3B Medical Inc. v. SoClean, Inc.*, No. 1:19-cv-03545-KPF

Dear Judge Failla:

3B Medical requests a pre-motion discovery conference to discuss its First Set of Requests for Production ("RFPs") (Ex. 1). Through its Objections (Ex. 2), SoClean seeks to unreasonably limit the scope of discovery. The parties met and conferred by telephone and email, but were unable to reach an agreement on the issues presented below.

SoClean sells CPAP-machine sanitizing devices that generate and emit ozone, a toxic gas that damages the lungs, which the FDA and EPA tightly regulate.[1] Compl. ¶¶ 11-92 (ECF No. 1). Despite this, SoClean aggressively markets its devices to consumers with sleep apnea, a population particularly vulnerable to cardio-pulmonary illness, for use in their bedrooms. *Id.* ¶¶ 15-17, 144-45. In its marketing materials, SoClean has gone to great lengths to conceal the existence and danger of ozone in its devices. For example, it falsely represents the devices use "activated oxygen," which suggest that ozone is a healthy kind of oxygen (it's not). *Id.* ¶¶ 96-109. SoClean compounds this falsehood by representing (among other things) that the devices are safe, healthy, and use no chemicals. *Id.* ¶¶ 110-140. And when SoClean does mention its use of ozone, it claims that "[o]zone is [] 100% safe..." *Id.* ¶ 125(c). SoClean's campaign of misrepresentations has worked—securing the company a dominant market position. *Id.* ¶¶ 141-49. Absent its false and misleading advertising, consumers—particularly the vulnerable market segment that SoClean targets—would not have widely adopted the SoClean devices, and 3B would have secured more sales and a greater market share. *Id.*

SoClean's Proposed Temporal Limits (RFPs 1-7, 9-10). For a number of requests, SoClean refuses to produce documents predating January 1, 2018 (shortly before 3B's competing device entered the market) or post-dating April 22, 2019 (when 3B filed this suit). However, 3B requested documents from "January 1, 2011 through the present" (Ex. 1, Instructions ¶ 1) because evidence shows that SoClean's misrepresentations began by January 2012 at the latest and continue today. *E.g.*, Jan. 9, 2012 SoClean Press Release (Ex. 3 at 1) ("The SoClean CPAP sanitizing unit generates activated oxygen..."); June 3, 2019 SoClean, Press Release (Ex. 4 at 3) ("SoClean's patented design and activated oxygen technology kills up to 99.9 percent of CPAP germs..."). Documents concerning the advent of SoClean's misrepresentations would go back to

[1] *See, e.g.*, FDA Ozone Rule, 21 C.F.R. § 801.415 (2019); EPA, *Ozone Generators that Are Sold as Air Cleaners*, https://bit.ly/2YJoH7l ("When inhaled, ozone can damage the lungs. Relatively low amounts of ozone can cause chest pain, coughing, shortness of breath and, throat irritation. It may also worsen chronic respiratory diseases such as asthma as well as compromise the ability of the body to fight respiratory infections."); Natalie Jacewicz, *A Killer of a Cure*, SCI. HIST. INSTITUTE (April 10, 2017), https://bit.ly/2z1hmnX (discussing the history of using false advertising to market ozone generators to consumers).

2011. And documents post-dating April 22, 2019 are relevant because SoClean's misconduct is ongoing and 3B is seeking a permanent injunction, which requires continuing harm to the plaintiff. Moreover, nothing renders a document (e.g., testing on the devices' ozone output) irrelevant simply because it occurred after the suit commenced.

SoClean mistakenly asserts discovery pre-dating January 1, 2018 is limited by the date 3B's competing device entered the marketplace, an argument based on the "injury" element of a Lanham Act claim. But that inquiry considers whether "the cause of action in §1125(a) extend[s] to plaintiffs like [3B]," *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129 (2014), a requirement sometimes called statutory or prudential standing, *see id.* at 125-28 & n.4. It limits who can bring a claim—not the claim itself. *See id.* at 129 ("The zone-of-interests test is therefore an appropriate tool for determining who may invoke the cause of action in §1125(a)."). 3B's March 2018 entry to the market made it an appropriate plaintiff, but 3B's status as a new entrant does not limit the scope of SoClean's Lanham Act violation. And even if SoClean's pre-2018 advertising were not at issue in the case, the requested documents are relevant to the advent of SoClean's recent misrepresentations and would be discoverable anyway. *See Church & Dwight*, No. 14-cv-585 (AJN), slip op. at 2-3 (S.D.N.Y. June 25, 2014), ECF No. 117 ("even if . . . [plaintiff] is barred . . . from bringing certain claims, this does not mean that [plaintiff] is barred from seeking discovery to the extent it is relevant to claims it can bring").

SoClean's Proposed Subject Matter Limitations (RFPs 1-3, 6, 7): 3B seeks all documents concerning the devices' design, operation, efficacy, and safety (RFP 1); product testing (RFP 2); marketing, promotion, packaging, and consumer perception (RFP 3); studies, polls, focus groups, surveys, or other method of gauging consumer impressions (RFP 6); and customer complaints and/or inquiries regarding the SoClean devices, filter cartridges, ozone, or activated oxygen (RFP 7). However, SoClean objected to these requests as overbroad and sought to limit each to only those responsive documents "concerning the six purportedly 'false and misleading representations' as asserted in paragraphs 97 to 137 of the Complaint." First, this is insufficient because 3B's claims are not strictly limited to those misrepresentations. *See* Compl. ¶ 138 ("SoClean has made additional false and misleading representations about the SoClean devices similar to those alleged in paragraphs 96 to 137."). Second, the proposal is ripe for abuse—SoClean cannot pick and choose, in secret, which documents to turn over based on its own self-serving interpretation of the Complaint. And because documents withheld on the basis of relevance are not logged, 3B would never know if there was a document that was relevant but not produced.

RFP 2: 3B seeks "[a]ll documents concerning any and all testing done on the SoClean devices and/or filter cartridges, whether before or after introduction to the market." In response, SoClean lodged a boilerplate overbreadth objection, which is improper. *See Leibovitz v. City of N.Y.*, 2017 U.S. Dist. LEXIS 15662, at *4-6 (S.D.N.Y. Feb. 3, 2017) (collecting cases and holding that "[b]ecause such objections violate Fed. R. Civ. P. 34(b)(2)(B), they are stricken"). And the requested information is relevant because it bears on how the products work, their safety, and SoClean's knowledge of those facts.

RFP 4: 3B seeks "[a]ll documents concerning ozone, O_3, or activated oxygen." However, SoClean objected and offered to produce only "documents concerning the *representations or disclosures* that the SoClean devices use ozone, O_3, or activated oxygen." Ex. 2 at 7 (emphasis added). This response is plainly insufficient, because Plaintiffs are entitled to discovery regarding what SoClean *knows* (not just what it represents) about ozone, O_3, and activated oxygen, because

it is relevant to whether SoClean's misrepresentations were intentional or made in bad faith. *E.g.*, *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 256 (2d Cir. 2014) (evidence "that a defendant has intentionally set out to deceive the public, and the defendant's 'deliberate conduct' in this regard is of an 'egregious nature'" is proof of consumer confusion).

RFP 6: 3B seeks "[a]ll documents constituting or concerning any studies, polls, focus groups, surveys, or other method of gauging consumer impressions of actual or proposed SoClean advertisements or marketing efforts." SoClean, however, objected to producing any proposed advertising unless it was responsive to another request. However, proposed advertising or marketing efforts are relevant to SoClean's state of mind and will show whether the company intentionally misled consumers or acted in bad faith, which is evidence of falsehood and materiality. *See Gnosis S.p.A.*, 760 F.3d at 256.

RFP 8: 3B seeks "[a]ll documents concerning Plaintiff 3B Medical, Inc. and its device, "the Lumin." SoClean lodged a boilerplate objection and refused to produce any documents pursuant to RFP 8. This is insufficient because the materials are relevant to show competition between the products, the degree to which SoClean's ozone generation distinguishes them, and its reaction to 3B's advertisements designed to bring public awareness to SoClean's use of ozone.

RFP 11: 3B seeks "[a]ll documents concerning the market discontinuance of the SoClean 2 Go," which occurred in or around January 2019. SoClean, however, objected in full to the request. When 3B explained that it believes that the SoClean 2 Go was withdrawn from the marketplace for safety reasons, SoClean demanded that 3B provide "evidence" as a precondition to complying with the request. This puts the cart before the horse. 3B issued the request to gather such evidence, which is uniquely within SoClean's sole possession.[2] And the documents are relevant to whether the device is unsafe, whether SoClean knows that, and to 3B's claim for punitive damages under New York law, which requires "a high degree of moral turpitude." *See Tiffany & Co. v. Costco Wholesale Corp.*, 127 F. Supp. 3d 241, 261 (S.D.N.Y. 2015). And, regardless, the requested documents are relevant to marketplace conditions.

RFP 12: 3B seeks "[a]ll communications with a government agency, including the Food and Drug Administration, concerning the SoClean devices and/or filter cartridges." Plaintiffs have agreed to limit this request to communications with regulators in the US and the EU. SoClean, however, objects that producing communications with regulators in the EU would be unduly burdensome. But this objection is unsubstantiated. And any burden should be minor, given that SoClean represented that it only communicates with the FDA in the US and given that EU member countries coordinate their regulation of these devices.

RFP 13: 3B seeks "[a]ll documents concerning the Food and Drug Administration or its regulations." In response, SoClean lodged a boilerplate objection, which is improper, *Leibovitz*, 2017 U.S. Dist. LEXIS 15662, at *4-6, and later agreed to produce only communications with the FDA. This is insufficient because SoClean's documents concerning the FDA and its regulations bear on the safety of the SoClean devices, their capacity to generate ozone, and SoClean's knowledge of those facts.

[2] And 3B notes that during the meet and confer process, SoClean would not confirm that the withdrawal was *not* safety related and counsel declined to confer with his client about it.

Sincerely,

Daniel Kotchen
Kotchen & Low, LLP

CC: All Counsel (via ECF)

Enclosures: 3B's First Set of Requests for Production of Documents (Ex. 1); SoClean's Responses (Ex. 2); Jan. 9, 2012 SoClean Press Release (Ex. 3); June 3, 2019 SoClean Press Release (Ex. 4).